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EXAMINER	
WILLIS, DOUGLAS M	

ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,916	STYLES ET AL.	
	Examiner	Art Unit	
	DOUGLAS M. WILLIS	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-13* is/are pending in the application.

4a) Of the above claim(s) *7 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-6 and 10-13* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

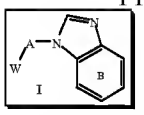
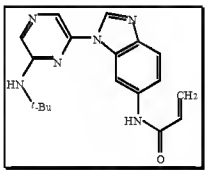
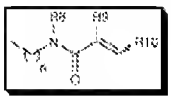
1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03-08-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims / Priority

Claims 1-7 and 9-13 are pending in the current application. According to the *Amendments to the Claims*, filed May 12, 2009, claims 1 and 2 were amended and claim 8 was cancelled. This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/AU2005/000022, filed January 12, 2005, which claims priority under 35 U.S.C. § 119(a-d) to AU 2004900103, filed January 12, 2004.

Restrictions / Election of Species

Applicant's provisional election of the following, without traverse, in the reply filed on  May 12, 2009, is acknowledged: a) Group I - claims 1-6 and 10-13; and b) substituted benzimidazole of formula I - p. 40, example 20, shown right below, and hereafter referred to as *N*-(1-(6-(*tert*-butylamino)pyrazin-2-yl)-1*H*-benzo[*d*]imidazol-6-yl)acrylamide, where **A = -pyrazinyl**; W = $-NR^1R^2$, wherein R^1 = -H and R^2 = -*t*-Bu; Y = -H; and Z is shown to the left below, wherein n = 0, R^8 = -H, R^9 = -H and R^{10} = -H.   Claims 1-6 and 10-13 read on the elected species. Affirmation of this election must be made by applicant in replying to this Office action.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7 and 9 were withdrawn from further consideration, pursuant to 37 CFR 1.142(b), as being drawn to a nonelected or cancelled invention, there being no allowable generic or linking claim.

Thus, a first Office action on the merits of claims 1-6 and 10-13 is contained within.

Specification Objection - Disclosure

Applicant is advised to format the specification according to 37 CFR 1.77(b). Revisions should particularly address bold-type formatting. Appropriate correction is required.

Specification Objection - Title

Applicant is reminded of the proper content of the title of the invention.

The title of the invention should be brief, but technically accurate and descriptive, preferably from two to seven words. See 37 CFR 1.72(a) and MPEP § 606.

The title of the invention is not technically accurate and descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. In the revised title, the examiner suggests identifying the substituted benzimidazoles of the formula I.

Specification Objection - Abstract

Applicant is reminded of the proper content of an abstract of the disclosure.

With regard particularly to chemical patents, for compounds or compositions, the general nature of the compound or composition should be given as well as the use thereof, e.g., *The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics.* Exemplification of a species could be illustrative of members of the class. For processes, the reactions, reagents and process conditions should be stated, generally illustrated by a single example, unless variations are necessary. See MPEP § 608.01(b), Section B.

The abstract of the disclosure is objected to because it because it should be amended to reflect the scope of the *Requirement for Restriction / Election of Species*, mailed on April 13, 2009. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claim 3 is objected to because of the following informalities: the claim lacks compliance with the *Requirement for Restriction / Election of Species*, mailed on April 13, 2009. Appropriate correction is required.

Claims 4, 5 and 10-13 are independently objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claims, amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form. The intended use of a substituted benzimidazole of formula I, as a selective inhibitor of JAK-3 kinase, is not found to be further limiting, since the intended use is not given patentable weight.

Claim Rejections - 35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Prodrugs, hydrates, solvates and crystal forms of substituted benzimidazoles and pharmaceutical compositions of the formula I

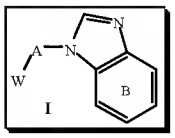
Claims 1, 2, 4-6 and 10-13 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for substituted benzimidazoles and pharmaceutical compositions of the formula I, does not reasonably provide enablement for *prodrugs*, *hydrates*, *solvates* and *crystal forms* of substituted benzimidazoles and pharmaceutical compositions of the formula I. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. *Prodrugs*, *hydrates*, *solvates* and *crystal forms* of substituted benzimidazoles and pharmaceutical compositions of the formula I, as recited in claim 1, have not been adequately enabled in the specification to allow any person having ordinary skill in the art, at the time this invention was made, to make and use *prodrugs*, *hydrates*, *solvates* and *crystal forms* of substituted benzimidazoles and pharmaceutical compositions of the formula I.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is *undue*. These factors include, but are not limited to: (a) breadth of the claims; (b) nature of the invention; (c) state of the prior art; (d) level of one of ordinary skill in the art; (e) level of predictability in the art; (f) amount of direction provided by the inventor; (g) existence of working examples; and (h) quantity of experimentation needed to make or use the invention based on the content of the disclosure. {See *Ex parte Forman* 230 USPQ 546 (Bd. Pat. App. & Inter. 1986); and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988)}.

The above factors, regarding the present invention, are summarized as follows:

(a) *Breadth of the claims* - the breadth of the claims includes all of the tens of thousands of substituted benzimidazoles and pharmaceutical compositions of the formula I, shown right, as well as the myriad of potential *prodrugs*, *hydrates*, *solvates* and *crystal forms* formulated from these substituted benzimidazoles and pharmaceutical compositions of the formula I, respectively;



I

(b) *Nature of the invention* - the nature of the invention is evaluation of *prodrugs*, *hydrates*, *solvates* and *crystal forms* of substituted benzimidazoles and pharmaceutical compositions of the formula I and the pharmacokinetic behavior of these substances in the human body as selective kinase inhibitors;

(c) *State of the prior art* - *Nature Reviews: Drug Discovery* offers a snapshot of the state of the drug development art. Herein, drug development is stated to follow the

widely accepted Ehrlich model which includes: 1) development of a broad synthetic organic chemistry program; 2) subsequent testing of compounds in an appropriate laboratory model for the disease to be treated; and 3) screening of compounds with low toxicity in prospective clinical trials (Jordan, V. C. *Nature Reviews: Drug Discovery,* 2, **2003**, 205);

(d) *Level of one of ordinary skill in the art* - the artisans synthesizing applicant's *prodrugs*, *hydrates*, *solvates* and *crystal forms* of substituted benzimidazoles and pharmaceutical compositions of the formula I, would be a collaborative team of synthetic chemists and/or health practitioners, possessing commensurate degree level and/or skill in the art, as well as several years of professional experience;

(e) *Level of predictability in the art* - Synthetic organic chemistry is quite unpredictable (*In re Marzocchi and Horton* 169 USPQ at 367 ¶ 3). The following excerpt is taken from Dörwald, which has extreme relevance to the *prodrugs*, *hydrates*, *solvates* and *crystal forms* of substituted benzimidazoles and pharmaceutical compositions of the formula I (Dörwald, F. Zaragoza. *Side Reactions in Organic Synthesis: A Guide to Successful Synthesis Design*, Weinheim: WILEY-VCH Verlag GmbH & Co. KGaA, **2005**, Preface):

Most non-chemists would probably be horrified if they were to learn how many attempted syntheses fail, and how inefficient research chemists are. The ratio of successful to unsuccessful chemical experiments in a normal research laboratory is far below unity, and synthetic research chemists, in the same way as most scientists, spend most of their time working out what went wrong, and why.

Despite the many pitfalls lurking in organic synthesis, most organic chemistry textbooks and research articles do give the impression that organic reactions just proceed smoothly and that the total synthesis of complex natural products, for instance, is maybe a labor-intensive but otherwise undemanding task. In fact, most syntheses of structurally complex natural products are the result of several years of hard work by a team of chemists, with almost every step requiring careful optimization. The final synthesis usually looks quite different from that originally planned, because of unexpected difficulties encountered in the initially chosen synthetic sequence. Only the seasoned practitioner who has experienced for himself the many failures and frustrations which the development (sometimes even the repetition) of a synthesis usually implies will be able to appraise such work.

Chemists tend not to publish negative results, because these are, as opposed to positive results, never definite (and far too copious).

Similarly, the following excerpt is taken from Vippagunta, et al. with respect to the synthesis of *solvates* and *hydrates* of substituted benzimidazoles and pharmaceutical compositions of the formula I (Vippagunta, et al. *Advanced Drug Delivery Reviews*, 48, **2001**, p. 18):

Predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated into the crystal lattice of a compound is complex and difficult. Each solid compound responds uniquely to the possible formation of solvates or hydrates and hence generalizations cannot be made for a series of related compounds. Certain molecular shapes and features favor the formation of crystals without solvent; these compounds tend to be stabilized by efficient packing of molecules in the crystal lattice, whereas other crystal forms are more stable in the presence of water and/or solvents. There may be too many possibilities so that no computer programs are currently available for predicting the crystal structures of hydrates and solvates.

Moreover, the following excerpt is taken from Burger's with respect to the synthesis of *prodrugs* of substituted benzimidazoles and pharmaceutical compositions of the formula I (Wolff, Manfred E., Ed. *Burger's Medicinal Chemistry and Drug Discovery - Fifth Edition,* New York: John Wiley & Sons, **1996**, vol. 1, pp. 975-976):

The design of prodrugs in a rational manner requires that the underlying causes which necessitate or stimulate the use of the prodrug approach be defined and clearly understood. It may then be possible to identify the means by which the difficulties can be overcome. The rational design of the prodrug can thus be divided into three basic steps: (1) identification of the drug delivery problem; (2) identification of the physiochemical properties required for optimal delivery; and (3) selection of a prodrug derivative that has the proper physiochemical properties and that will be cleaved in the desired biological compartment.

The difficulty of extrapolating data from animal to humans encountered during toxicokinetic and toxicologic studies with drugs is amplified with prodrugs, since not only metabolism of the active moiety might differ, but also its availability from the prodrug. As a matter of fact, there is presently no published rational for the conduct of animal and human pharmacokinetic programs during prodrug research and development.

Finally, the following excerpt is taken from Chawla, et al. with respect to the synthesis of *crystal forms (polymorphs)* of substituted benzimidazoles and pharmaceutical compositions of the formula I (Chawla, et al. *Curr. Res. & Info. Pharm. Sci.* (*CRIPS)*, 5, *1*, **2004**, pp. 9-12):

Polymorphism is the ability of a substance to exist in two or more crystalline phases that have different arrangement and/or conformation of molecules in the crystal lattice. However, they share a common form once they are in the solution phase. It can significantly affect the physiochemical, formulation and processing parameters, as well as the shelf life (stability) of the drug substance and excipients.

Polymorphism has contributed significant variability in product performance in pharmaceutical, chemical and food industry and continues to pose a challenge to

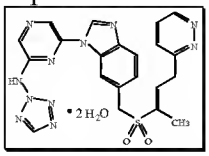
pharmaceutical scientists in producing drugs of consistent quality. An inadvertent production of the 'wrong' polymorph at the crystallization stage or any transformations of one form to another during dosage form processing, storage and scale-up can result in pharmaceutical dosage forms which are either ineffective or toxic.

(f) *Amount of direction provided by the inventor* - the application is negligent regarding direction with respect to making and using *prodrugs*, *hydrates*, *solvates* and *crystal forms* of substituted benzimidazoles and pharmaceutical compositions of the formula I;

(g) *Existence of working examples* - applicant has provided sufficient guidance to make and use substituted benzimidazoles and pharmaceutical compositions of the formula I; however, the disclosure is insufficient to allow extrapolation of the limited examples to enable the scope of the tens of thousands of *prodrugs*, *hydrates*, *solvates* and *crystal forms* of substituted benzimidazoles and pharmaceutical compositions of the formula I. The specification lacks working examples of *prodrugs*, *hydrates*, *solvates* and *crystal forms* of substituted benzimidazoles and pharmaceutical compositions of the formula I.

Within the specification, "specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. *Markush* claims must be provided with support in the disclosure for each member of the *Markush* group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula." See MPEP § 608.01(p).

(h) *Quantity of experimentation needed to make or use the invention based on the content of the disclosure* - predicting whether a *prodrug*, *hydrate*, *solvate* or *crystal form* of a recited compound is in fact one that produces a desired physiological effect at a therapeutic concentration and with useful kinetics, is filled with experimental uncertainty, and without proper guidance, would involve a substantial amount of experimentation (Jordan, V. C. *Nature Reviews: Drug Discovery,* 2, **2003**, 205-213). Furthermore, it is unclear, based on the guidance provided by the specification, whether a substituted benzimidazole of the formula I, such as (*E*)-6-(6-((4-(pyridazin-3-yl)but-2-en-2-ylsulfonyl)methyl)-1*H*-benzo[*d*]imidazol-1-yl)-*N*-(2*H*-tetrazol-2-yl)-pyrazin-2-amine dihydrate, shown to the left above, is either synthetically feasible or possesses utility in the human body as a selective kinase inhibitor.



A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught

one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. {See *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)}.

The determination that *undue experimentation* would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. (See *In re Wands,* 858 F.2d at 737, 8 USPQ2d at 1404). These factual considerations are discussed comprehensively in MPEP § 2164.08 (scope or breadth of the claims), § 2164.05(a) (nature of the invention and state of the prior art), § 2164.05(b) (level of one of ordinary skill), § 2164.03 (level of predictability in the art and amount of direction provided by the inventor), § 2164.02 (the existence of working examples) and § 2164.06 (quantity of experimentation needed to make or use the invention based on the content of the disclosure).

Based on a preponderance of the evidence presented herein, the conclusion that applicant is insufficiently enabled for making and using *prodrugs*, *hydrates*, *solvates* and *crystal forms* of substituted benzimidazoles and pharmaceutical compositions of the formula I, is clearly justified.

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase *selective JAK-3 inhibitor*, in claims 10-13, respectively, is a relative phrase

which renders the claims indefinite. The phrase *selective JAK-3 inhibitor* is not defined by the claims, the specification does not provide an adequate standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification, on p. 10, references substituted benzimidazoles of the formula I as *selective JAK-3 inhibitors*, but the examiner is uncertain whether the phrase *selective JAK-3 inhibitor* is explicitly limited to these specifically disclosed embodiments. Thus, the recited phrase *selective JAK-3 inhibitor* is simply indefinite in claims 10-13. Moreover, during this Office action, the phrase *selective JAK-3 inhibitor* has been interpreted to reference substituted benzimidazoles and pharmaceutical compositions of the formula I.

The examiner suggests limiting the phrase *selective JAK-3 inhibitor* to substituted benzimidazoles and pharmaceutical compositions of the formula I, as discussed in the *Requirement for Restriction / Election of Species*, mailed on April 13, 2009, to overcome this rejection.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

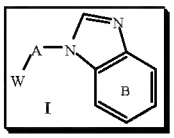
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

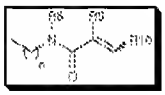
The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

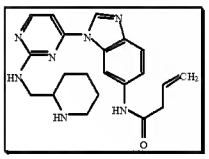
Claims 1, 2, 4-6 and 10-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Goulet, et al. in US 6,329,380.

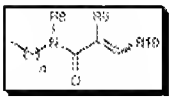
The instant application recites substituted benzimidazoles and pharmaceutical compositions of the formula I, shown to the left, where A = -pyrimidinyl; W = -NR^1R^2, wherein R^1 = -H and R^2 = -C_{1-4}alkylcyclohetalkyl; Y = -H and Z is shown to the right above, wherein n = 0, R^8 = -H, R^9 = -H and R^{10} = -H, as selective kinase inhibitors.





Goulet, et al. (US 6,329,380) teaches substituted benzimidazoles and pharmaceutical compositions of the formula I, shown to the left, where A = -pyrimidinyl; W = -NR^1R^2, wherein R^1 = -H and R^2 = -CH_2-piperidin-2-yl; Y = -H and Z is shown to the right above, wherein n = 0, R^8 = -H, R^9 = -H and R^{10} = -H, as SRC kinase inhibitors [column 83, example 48; and pharmaceutical compositions - column 24, lines 53-65].





The only difference between the instantly recited substituted benzimidazoles and pharmaceutical compositions of the formula I and Goulet's substituted benzimidazoles and pharmaceutical compositions of the formula I is the instantly recited substituted benzimidazoles and pharmaceutical compositions of the formula I and Goulet's substituted benzimidazoles and pharmaceutical compositions of the formula I are homologs, with respect to *Z*.

MPEP § 2144.09 states *compounds which are homologs, differing regularly by the successive addition of the same chemical group, e.g., by -CH_2- groups, are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds*

possess similar properties. {See *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977)}.

Likewise, in the chemical arts, it is widely accepted that *structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions or compounds, creates a prima facie case of obviousness*. {See *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, No. 06-1329, slip op. at 9 (Fed. Cir. June 28, 2007) (quoting *In re Dillon*, 919 F.2d 688, 692 [16 USPQ2d 1897] (Fed. Cir. 1990) (en banc)); and *In re Papesch*, 315 F.2d 381 [137 USPQ 43] (C.C.P.A. 1963)}.

Moreover, the courts have further recognized that *when expectation of similar properties stands unrebutted, it necessarily follows that expectation of similar uses also stands unrebutted, [with] expectation of similar use necessarily implying expectation of substantially equivalent substitutes. Furthermore, there is no logical basis for distinguishing patentably between a prior art [homologous] compound and a claimed novel compound prima facie obvious therefrom, even where a previously unknown or unobvious use has been found, where that use nevertheless inheres in both compounds and it is the compound per se that is claimed*. {See *In re Hoch*, 57 CCPA 1292, 428 F.2d 1341, 166 USPQ 406 (1970)}.

Consequently, since: a) Goulet teaches substituted benzimidazoles and pharmaceutical compositions of the formula I, which are homologous, with respect to *Z*, with the instantly recited substituted benzimidazoles and pharmaceutical compositions of the formula I; b) MPEP § 2144.09 states c*ompounds which are homologs, differing regularly by the successive addition of the same chemical group, e.g., by -CH_2- groups, are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties*;

c) the courts have recognized that *structural similarity between claimed and prior art subject matter, where the prior art gives reason or motivation to make the claimed compositions or compounds, creates a prima facie case of obviousness*; and d) the courts have further recognized that *when expectation of similar properties stands unrebutted, it necessarily follows that expectation of similar uses also stands unrebutted, [with] expectation of similar use necessarily implying expectation of substantially equivalent substitutes*, one having ordinary skill in the art, at the time this invention was made, would have been motivated to utilize the teachings of Goulet and formulate homologs of Goulet's substituted benzimidazoles and pharmaceutical compositions of the formula I, with a reasonable expectation of success and similar therapeutic activity, rendering claims 1, 2, 4-6 and 10-13 obvious.

Finally, although not explicitly discussed herein, applicant is advised to note that the Goulet reference contains additional species representative of substituted benzimidazoles and pharmaceutical compositions of the formula I. Consequently, any amendments to the claims to overcome rejections rendered under 35 U.S.C. § 103(a) should address this reference as a whole and should not be limited to the species discussed or disclosed explicitly herein.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claim Rejections - Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute), so as to prevent the unjustified or improper timewise extension of the *right to exclude* granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claims because the examined application claim is either anticipated by, or would have been obvious over, the reference claims. {See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969)}.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-6 and 10-13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 7 and 13-19 of

copending Application No. 10/581,412. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 in the copending application recites definitions for *D, A, Q* and *W*, which provide overlapping subject matter with respect to the instant claims. For example, if *D* is benzimidazolyl in claim 1 of the copending application, then the genus of the copending application is commensurate in scope with the genus of the instant application, with respect to the substituted benzimidazoles and pharmaceutical compositions of the formula I.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DOUGLAS M. WILLIS, whose telephone number is 571-270-5757. The examiner can normally be reached on Monday thru Thursday from 8:00-6:00 EST. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson, can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DOUGLAS M WILLIS/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624